K010851

SEP 1 8 2001

Sanghak O. Harrison, DC
Harruison CBP Seminars.
PO Box 1590
Evanston, WY 82931-1590

July 10, 2001

Subject: 510(k) Summary

1) The 510(k) preparer or contact person is Sang Harrison, DC, and the 510(k) applicant or submitter is Alfred Ueda, DC. Mrs. Harrison may be contacted at the above address, by telephone at 307-789-2088, or by FAX at 307-789-2154. Al Ueda may be contacted at 145 Uplands Circle, Conte Madena, CA 94925, ph: 415-945-3216
2) **Trade Name:** Harrison Hand Held Adjusting Instrument
Common Name: Hand Held Adjusting instrument
Classification Name: Chiropractic adjusting instrument, manipulator, plunger-like joint, non-powered, non-invasive
3) The following is a list of Predicate Devices, which we are claiming Substantial Equivalence (SE) to. These include, but are not limited to, devices with the following 510(k) Numbers: **K955540** (Hand-held Spinalight), **K930431** (Arthrostim), **K951217** (Atlas Orthogonal) & **K973506** (Activator II).
4) **Description of the Device:** The Harrison Hand Held Adjusting Instrument is made up of a high impact plastic body surrounding the electrical component. The electrical component has not been altered from the original manufacturer, which is already UL approved and thus maintains the original standards of safety. A metal rod or stylus protrudes from the body of the instrument and is covered with a rubber tip at the contact point for patient comfort. The instrument is a solenoid-activated device capable of generating only one (1) cycle/sec. The handle of the body of the instrument is 5 ½" in length, the body which houses the electrical component is 5 ¼" in length & 2 ¼" tall, and the stylus protruding from the body is 4 ¼" long. The knob at the opposite end to the stylus adjusts the penetrating depth of the stylus by ¼". The attached picture serves to illustrate what the adjusting instrument looks like.

5) **Intended Uses of the Device:** A review of literature shows that medical uses of the listed Predicate Devices (i.e. Handheld Spinalator, Arthrostim, and Activator II) include manipulation of spinal joints (facet joints) and chiropractic adjustment of subluxations. Thus, the indications of use for the Harrison Hand-held Adjusting Instrument are identical to those of the Predicate Devices. Therefore, the Harrison Hand Held Adjusting Instrument should be viewed as a conservative treatment alternative, which does not raise any new safety and effectiveness issues. The clinical data collected further supports the safety and effectiveness of this new adaptation for spinal manipulation devices, showing that this device demonstrates a more predictable amount of applied force. Please see # 7 below for supporting evidence.
6) **Technological Characteristics:** The technological characteristics of our device compared to the Predicate Devices are essentially the same. The Harrison Hand Held Adjusting Instrument generates only one (1) cycle/sec, and the Predicate Device(s) generate 12 cycles/sec. Therefore, the Harrison Hand Held Adjusting Instrument is a new, safe and effective spinal adjusting instrument with technological characteristics similar, if not identical, to the Predicate Device(s).
7) **Discussion of Clinical Study:** The following is a brief discussion of the clinical trial conducted utilizing the Harrison Hand Held Adjusting Instrument. The clinical data is currently being analyzed at the Universite du Quebec a Trois-Rivieres by Martin Normand, PhD, DC, with the help of Tony Keller, PhD (University of Vermont, Mechanical Engineering Department). The purpose of this investigation is to verify the kinetic energy delivered by the Harrison Hand Held Adjusting Instrument in comparison with a spring-activated device, such as the Activator II (**K973506**). Preliminary data shows that the solenoid has similar capabilities to that of the spring, and it is not dependant upon expansion of the spring for force generation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Sanghak O. Harrison, DC
Harrison CBP Seminars
P.O. Box 1590
Evanston, Wyoming 82931

SEP 1 8 2001

Re: K010851
Trade/Device Name: Harrison Hand Held Adjusting Instrument
Regulatory Class: Unclassified
Product Code: LXM
Dated: July 13, 2001
Received: July 19, 2001

Dear Mr. Harrison:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Neil R.P. Ogden for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use Statement

Applicant: Alfred Ueda, DC

510(k) Number (if known): K010851

Device Name: Harrison Hand Held Adjusting Instrument

Indications For Use:

The Harrison Hand Held Adjusting Instrument is intended for use as a conservative chiropractic treatment for spinal subluxation or simply put, manipulation of spinal joints (facet joints). The target population includes any human subject with the aforementioned condition(s). The device can be used in any number of clinical settings including chiropractic offices, physical therapy offices, orthopedic/medical offices, and hospitals.

NRO for CMW

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010851

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)